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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,763	12/05/2001	Jon A. Wolff	MIRUS.003.06.2	8462

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

10/004,763

Applicant(s)

WOLFF ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears n th c ver sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method of making a complex for delivery (of a compound) to a cell, classified in class 435, subclass 91.1+.
- II. Claim 6, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is an orthogonal protecting group or a hydrogen, and R' is an orthogonal protecting group, a hydrogen, a reporter molecule or a targeting group, classified in class 423, subclass 364.
- III. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a vinyl group, classified in class 423, subclass 364.
- IV. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is an acrylate group, classified in class 423, subclass 364.
- V. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a methacrylate group, classified in class 423, subclass 364.
- VI. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is an acrylamide group, classified in class 423, subclass 364.
- VII. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a methacrylamide group, classified in class 423, subclass 364.

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- VIII. Claim 7, drawn to a monomer comprising at least the recited tertiary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a targeting group, classified in class 423, subclass 364.
- IX. Claim 8, drawn to a monomer comprising at least the recited secondary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a vinyl group, classified in class 423, subclass 364.
- X. Claim 8, drawn to a monomer comprising at least the recited secondary amine core structure, wherein R is a protecting group or a hydrogen, and R' is an acrylate group, classified in class 423, subclass 364.
- XI. Claim 8, drawn to a monomer comprising at least the recited secondary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a methacrylate group, classified in class 423, subclass 364.
- XII. Claim 8, drawn to a monomer comprising at least the recited secondary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a acrylamide group, classified in class 423, subclass 364.
- XIII. Claim 8, drawn to a monomer comprising at least the recited secondary amine core structure, wherein R is a protecting group or a hydrogen, and R' is a methacrylamide group, classified in class 423, subclass 364.
- XIV. Claims 9 and 10, drawn to a polymer comprising a nucleic acid-binding monomer, two linkers which are aliphatic, cycloaliphatic or aromatic, and one or two bonds from the recited list, classified in class 424, subclass 450.

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The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group XIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method may be used to make other polymers, and the polymers may be made by another method, e.g., a method wherein the polyion is absent during polymerization.

Inventions of Groups II-XIII and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monomers may be used to make a different polymer, e.g., one with different linkers and chemical bonds between said linkers, and the process of making may be used to polymerize different monomers.

Inventions of Group XIV and Groups II-XIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the recited monomer in the polymer is more broadly drawn than the monomer claims, and because the polymer recites another component which could confer patentability over the monomers, i.e., the linker components or

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the recited chemical bond between said linker components. The subcombination has separate utility such as polymerization into a patentably distinct polymer excluded by the polymer claims of Group XIV, e.g., a co-polymer, or as a linker molecule itself to attach a molecule to a surface or support.

Inventions of Groups II-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different linkages by virtue of their mutually exclusive R or R' groups, and thus would represent mutually exclusive inventions. Furthermore, the different R or R' groups would have potentially different biological properties.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the searches required for Groups II-XIII are mutually exclusive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk  
July 17, 2003



JAMES KETTER  
PRIMARY EXAMINER